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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,052	11/22/2006	Kimihiro Mabuchi	19461-004US1 547267	2047
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EXAMINER				
CHRISTIAN, MARJORIE ELLEN				
ART UNIT		PAPER NUMBER		
1797				
NOTIFICATION DATE		DELIVERY MODE		
09/29/2009		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary

Application No.

10/582,052

Applicant(s)

MABUCHI ET AL.

Examiner

MARJORIE CHRISTIAN

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SE/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. The amendment filed 9/9/2009 has been entered and fully considered.
2. **Claims 1-7** are pending and have been fully considered.

Double Patenting

3. **Claims 1-7** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over:

- Claims 1-9 of copending Application No. 10/559,544; and
- Claims 1-6, 16-17 of copending Application No. 10/599,167.

Although the conflicting claims are not identical, they are not patentably distinct from each other because each of the copending applications and the instant application disclose a hollow fiber membrane apparatus. The apparatus of the copending applications relate to hollow fiber membranes for dialysis with a hydrophobic and hydrophilic polymer that comprise at least some of the following features: the amount of hydrophilic polymer eluted, mass of hydrophilic polymer on the outer surface; and testing procedures that imply specific characteristics for hollow fiber membrane. Many of the features (various structural limitations) claimed in the instant and copending applications may not be explicitly present but are inherent or implicit. If the copending application claims an apparatus relating to hollow fiber membranes for dialysis with some of the specific features recited above, then there is obviousness-type double patenting as it would have been obvious to one of ordinary skill in the art at the time the

invention was made to have run applicant's particular recited apparatus, as taught either independently or in combination by the copending applications as selection of any of these known equivalents would be within the level of ordinary skill in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

4. **Claims 1-2, 4-7 are rejected under 35 USC 103 (a) as being obvious over EP 0 997 182, FUKE et al. (hereinafter FUKE) in view of US Patent No. 5,071,887, NAKAGAWA et al. (hereinafter NAKAGAWA) as further evidenced by US Patent No. 6,605,218 KOZAWA et al. (hereinafter KOZAWA).**

As to **Claim 1**, FUKE discloses a bundle of selectively permeable polysulfone-based hollow fiber membranes for purifying blood (Abstract) [*inner surface contacting blood and outer surface contacting dialysate*] wherein the amount of hydrophilic polymer eluted is inhibited by cross-linking using radiation (Paragraph 19, Page 4), such that the amount of water-soluble PVP becomes 5 to 50% of the total amount [*amount of hydrophilic polymer eluting from each hollow fiber is not larger than 10ppm*]. FUKE does not explicitly disclose that the elution rate is not larger than 10 ppm however it is implicit that the elution rate can be in that range, this is further evidenced by KOZAWA. KOZAWA discloses that the amount of hydrophilic polymer eluted is not higher than 10ppm (Abstract). FUKE also discloses that membrane contains 7 parts PVP and 17 parts polysulfone (specifically Example 1, see also all examples), therefore it is

derivable that the outer surface concentration of the PVP falls in the claimed range (30-45% of hydrophilic to hydrophobic polymer).

FUKE does not appear to expressly disclose the UV absorbance of the test solution obtained from pieces of fiber. However, NAKAGAWA discloses a test solution obtained from pieces of fiber to a length of 2 cm, where the solution is capable of being from ten fractions of the bundle obtained at regular lengthwise intervals, absent evidence to the contrary; the test method for eluted matter is based on Approval Standard for Dialysis-type Artificial Kidney (C6/L26-27); and it is implicit that the difference between the maximum and minimum out of the maximum values of UV absorbance of the extracted solution from the fractions is not larger than 0.05, absent evidence to the contrary, and in view of the fact that is desirable to reduce the amount of elution since the absorbance of the test solution is not more than 0.1 at a wavelength of 220 nm to 350 nm, (C6/L25-52).

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the polysulfone-based hollow fiber of FUKE to include the UV absorbance of the fibers in a test solution of NAKAGAWA. The motivation would have been to have a standard test method for eluted matter (C6/L25). Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

As to **Claim 2**, it is inherent that the hollow fiber bundle of FUKE (in view of NAKAGAWA) has *substantially no partial* sticking of the hollow fiber membranes in the lengthwise direction, absent evidence to the contrary. This is further evidenced by the

fact that the partial sticking occurs when the hydrophilic polymer content is high and that FUKU reduces the amount of hydrophilic content by a washing method (Page 6, Para. 30-31, 33-34) similar to that disclosed in the instant specification (where the washing method is for the express purpose of substantially reducing the partial sticking).

As to **Claim 4**, FUKU (in view of NAKAGAWA) discloses that the proportion of polyvinyl pyrrolidone to polysulfone is 1 to 10% by weight, where polyvinyl pyrrolidone is the hydrophilic polymer (Claim 1) *[mass ratio of hydrophilic polymer to polysulfone-based resin is 1 to 20 mass %]*.

As to **Claims 5-6**, FUKU (in view of NAKAGAWA) discloses that the hydrophilic polymer is poly(vinylpyrrolidone) (Abstract) and it is crosslinked by irradiation so that it is insolubilized (Page 4, Line 55).

As to **Claim 7**, FUKU (in view of NAKAGAWA) discloses that the hollow fiber membrane is for purifying blood (Page 3, Paragraph 11) *[bundle is used in a blood purifier]*.

5. **Claim 3** is rejected under 35 USC 103 (a) as being obvious over EP 0 997 182, FUKU et al. (hereinafter FUKU) in view of US Patent No. 5,071,887, NAKAGAWA et al. (hereinafter NAKAGAWA) in further view of US Patent No. 5,514,413, VAN'T HOFT et al. (hereinafter VAN'T HOFT).

As to **Claim 3**, FUKU (in view of NAKAGAWA) discloses a pore diameter distribution in the outer wall of the membrane (Para. 37-38). FUKU does not appear to explicitly disclose the specific range of the porosity on the outer surface. However,

VAN'T HOFT discloses a surface porosity of 1 to 20% (Column 3, Lines 6-7) [*porosity of the outer surface is 8 to 25%*].

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the porosity of the hollow fiber membrane of FUKU (in view of NAKAGAWA) to include the specific surface porosity of VAN'T HOFT. The suggestion would have been to have sufficient porosity to ensure nominal resistance to gas transport and have a polymeric substrate that meets the strength, thermal stability and process compatibility for the membrane (C3/L1-6). Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments and Affidavit/Declaration

6. Applicant's arguments filed 9/9/2009 and Affidavit/Declaration have been fully considered but they are not persuasive.

Applicant argues that the concentration of PVP on the outer surface of the hollow fiber membrane is not rendered obvious by FUKU. This is not found persuasive as the concentration of PVP is determined from the total amount of PVP and polysulfone, based on this it is derivable that the concentration of PVP disclosed by FUKU is within the range claimed by applicant (see examples and above rejection).

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: US Patent No. 5,340,480, KAWATA et al. discloses a polyvinylpyrrolidone and polysulfone membrane that meets the UV absorption standard based on the approval standards for artificial kidney apparatus (Ex. 1).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARJORIE CHRISTIAN whose telephone number is (571)270-5544. The examiner can normally be reached on Monday through Thursday 7-5pm (Fridays off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571)272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Krishnan S Menon/
Primary Examiner, Art Unit 1797

MC